



**U.S. Department of Justice**

**Michael J. Sullivan**  
*United States Attorney*  
*District of Massachusetts*

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse  
1 Courthouse Way  
Suite 9200  
Boston, Massachusetts 02210

September 11, 2007

Brien T. O'Connor  
Ropes & Gray  
One International Place  
Boston, MA 02109

Re: Express Scripts, Inc.

Dear Mr. O'Connor:

This letter sets forth the agreement (the "Agreement") between the United States Attorney's Office for the District of Massachusetts ("USAO") and Specialty Distribution Services, Inc., ("SDS").

**A. Introduction**

WHEREAS, in October 2000, SDS, a wholly owned subsidiary of Express Scripts, Inc. ("ESI"), was awarded a contract, by a pharmaceutical company, to distribute that pharmaceutical company's human growth hormone product.

WHEREAS, pursuant to that contract, SDS distributed human growth hormone to various physicians, clinics and individuals.

WHEREAS, thereafter the USAO conducted an investigation regarding potential criminal violations of the Food, Drug & Cosmetics Act ("FDCA") relating to the off-label prescription, sale and distribution of human growth hormone (the "Subject Matters"). During the course of the investigation, the USAO notified SDS that SDS, acting through certain of its employees, had violated federal criminal law by distributing human growth hormone for anti-aging, cosmetic or athletic performance enhancement uses, and that there is sufficient basis to seek an indictment of SDS, including for violation of 21 U.S.C. §333(e). In particular, the USAO notified SDS that certain instances in which prescriptions for human growth hormone were reviewed, approved, filled and shipped by SDS violated federal criminal law, specifically 21 U.S.C. §333(e), which is part of the FDCA. A description of these transactions is set forth in the Statement of Facts attached hereto as Appendix A.

WHEREAS, the USAO believes that SDS, through certain of its employees, distributed human growth hormone in violation of 21 U.S.C. §333(e), because SDS distributed human growth hormone to certain well-known athletes or entertainers for uses other than those for which human growth hormone had been approved by the United States Food & Drug Administration. In particular, as set forth in Appendix A, those instances of distribution were to well-known athletes and entertainers for athletic performance enhancement, cosmetic or anti-aging uses.

WHEREAS, the USAO has determined that SDS did not market or promote human growth hormone to these individual users, or their physicians, and SDS did not initiate contacts with any of these individual users, or their physicians, but that SDS did knowingly distribute human growth hormone to these individual users or their physicians, pursuant to a physician request.

WHEREAS, ESI and SDS have represented to the USAO that SDS has discontinued any distribution of human growth hormone for athletic performance enhancement, cosmetic or anti-aging use.

WHEREAS, ESI and SDS will provide semi-annual training to all SDS employees who in any way manage or handle human growth hormone prescriptions, which training specifically includes reference to 21 U.S.C. §333(e) and instruction that human growth hormone prescriptions may not legally be filled and distributed for any athletic performance enhancement, cosmetic or anti-aging uses.

WHEREAS, SDS has designated certain pharmacist employees to review every adult prescription for human growth hormone to ensure that no prescription is filled for any athletic performance, cosmetic or anti-aging uses.

WHEREAS, the USAO has determined that an indictment of SDS may cause undue harm to innocent individuals, including current employees, ESI clients and their members, and shareholders of ESI who had no involvement in the criminal conduct under investigation.

**B. SDS's Acceptance of Responsibility**

1. SDS admits to and accepts responsibility for its conduct and the conduct of its employees as set forth in Appendix A. SDS agrees that the conduct in Appendix A is accurate in its entirety and, as more fully addressed below, SDS agrees not to contradict Appendix A.
2. SDS agrees that, if it violates any terms of this Agreement, the USAO may file the attached criminal Information (the "Information") in the United States District Court for the District of Massachusetts charging SDS with violation of 21 U.S.C. §333(e). A copy of the Information is attached hereto as Appendix B.

3. SDS does not endorse, ratify, or condone any illegal conduct and, as set forth below, has taken steps to prevent such conduct from occurring in the future.
4. SDS will not, through its present or future directors, officers, employees, agents, attorneys, affiliates, parents or subsidiaries, make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in Appendix A. Any such contradictory public statement by SDS, its present or future directors, officers, employees, agents, attorneys, affiliates, parents or subsidiaries shall constitute a breach of this Agreement, and subject to the provisions in paragraph 5 below, SDS shall therefore be subject to prosecution on the Information attached to this Agreement.
5. The decision as to whether any public statement by any such person contradicting a statement contained in Appendix A will be imputed to SDS for the purpose of determining whether SDS has breached this Agreement shall be at the sole reasonable discretion of the USAO. Upon the USAO reaching a determination that such a contradictory statement has been made by SDS, the USAO shall so notify SDS in writing and SDS may avoid a breach of this Agreement by publicly repudiating such statement within five (5) days after written notification by the USAO. Consistent with the obligations set forth in this Agreement, SDS and/or ESI may take good faith positions in litigation or a dispute with a private party or governmental agency.

**C. SDS's Cooperation**

6. During the term of this Agreement, SDS agrees to cooperate fully with the USAO, and, as directed by the USAO, with any other federal, state or foreign law enforcement or regulatory agency regarding the Subject Matters. The duty to cooperate includes an affirmative duty of full and truthful disclosure. SDS shall truthfully disclose to the USAO all information respecting the activities of SDS and its present and former directors, officers, employees, agents, attorneys, affiliates, parents, and subsidiaries relating to Subject Matters about which the USAO may inquire, or which SDS reasonably believes is material to the investigation by the USAO. SDS agrees that its cooperation shall include, but is not limited to, the following:
  - (a) providing reasonable access to SDS's documents, facilities and directors, officers, employees, agents, affiliates and subsidiaries for matters relating to the investigation of the Subject Matters;
  - (b) assembling, organizing and producing, or taking reasonable steps to effectuate the production of, on request from the USAO, all documents, records, or other tangible evidence related to the investigation of the

Subject Matters in SDS's possession, custody or control in such reasonable format as the USAO requests;

- (c) using its reasonable best efforts to make available its present or former directors, officers, employees, agents, affiliates and subsidiaries to provide information and/or testimony related to the investigation of the Subject Matters as requested, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities. Cooperation under this sub-paragraph will include identification of witnesses who, to SDS's knowledge, may have material information regarding the investigation.
- (d) providing testimony and other information deemed necessary by the USAO or the court to establish the original location, authenticity, or other evidentiary foundation to admit into evidence documents relating to the Subject Matters in any criminal case or other proceeding as requested by the USAO; and
- (e) maintaining SDS as a lawfully organized and adequately capitalized corporate entity for purposes of this Agreement during the time this Agreement is in effect.

Nothing in this paragraph constitutes an agreement that SDS or ESI will waive the attorney-client privilege or work product protections.

**D. Mutual Obligations of SDS and USAO**

- 7. In exchange for the agreement of the USAO as set forth in paragraph 8 below, SDS agrees:
  - (a) to accept responsibility as set forth in paragraphs 1 to 5 above;
  - (b) to pay as a monetary penalty the amount of \$10.5 million to the United States Treasury. This payment is a material term of this Agreement. Failure to make payment upon execution of this Agreement (or within two business days of execution) renders all remaining terms of this Agreement null and void, except as set forth in paragraph 15;
  - (c) to undertake the training and compliance obligations described more fully in paragraphs 9 to 10 below; and
  - (d) to continue to cooperate with the USAO in its investigation of the matters described herein as more fully set forth in paragraph 6 above.

8. In light of SDS's remedial actions to date and its willingness to (a) acknowledge responsibility for the behavior of itself and its employees; (b) cooperate with the USAO and other governmental agencies; and (c) demonstrate its future good conduct and full compliance with the FDCA, and in exchange for SDS's agreement to fulfill the obligations described in this Agreement, the USAO agrees that if SDS is in full compliance with all of its obligations under this Agreement, the USAO will not prosecute SDS or ESI on the attached Information, on the matters described in the Statement of Facts, or for any other interactions with pharmaceutical manufacturers investigated by or known to the USAO.

**E. SDS' Training and Compliance**

9. Within ninety (90) days following the Effective Date of this Agreement, and as appropriate throughout the course of the Agreement, SDS shall commence semi-annual training to all of its management team and to all SDS employees who in any way manage or handle human growth hormone prescriptions. That training shall include specific reference to 21 U.S.C. §333(e), and shall explicitly explain that knowingly filling and shipping of any human growth hormone prescription for athletic performance enhancement, cosmetic or anti-aging uses could subject an individual or the Company to criminal prosecution.
10. Prior to the Effective Date of this Agreement and during the term of the Agreement, SDS shall designate (and identify to the USAO) certain pharmacist employees (heretofore not involved in any human growth hormone prescriptions) to review every adult (meaning eighteen (18) years of age or older) prescription for human growth hormone and confirm, before such prescription is filled and shipped, that no prescription is knowingly filled for any athletic performance, cosmetic or anti-aging uses. SDS shall keep written records of these reviews, which shall be provided to the USAO upon request.

**F. Breach of the Agreement**

11. For the term of this Agreement, should the USAO in its sole reasonable discretion, determine that SDS (a) has knowingly and willfully given false, incomplete or misleading information under this Agreement, (b) has committed any federal crimes subsequent to the date of this Agreement, or (c) has otherwise knowingly breached any provision of this Agreement (these three circumstances, (a), (b) and (c) are individually and collectively referred to herein as "Breach"), SDS shall, in the USAO's sole reasonable discretion, thereafter be subject to prosecution(s) for any federal criminal violations, including, without limitation, the Information. SDS waives any right it may have to proceed by way of indictment and waives any and all rights it may have under applicable statutes of limitation or other legal, equitable or constitutional limitations that may limit the period of time during which the USAO may seek an indictment or other charging

document (such as a complaint or other information) for the offenses covered by the Information. Moreover, with respect to any prosecutions relating to human growth hormone distribution that are not time-barred as of the date of this Agreement by the applicable statute of limitations (or any other legal, equitable or constitutional basis upon which a prosecution may be time-barred), SDS agrees to waive venue and any legal or procedural defects in the Information attached hereto as Appendix B, and agrees that the applicable statute of limitations period (or any other legal, equitable or constitutional basis for barring prosecution based on the passage of time), shall be tolled for a period of time equal to the term of this Agreement, in addition to the written tolling agreement between the parties dated May 16, 2007 (which excludes counting any time toward the running of the statute of limitations from September 11, 2006 through the date of this Agreement). Further, SDS shall waive any rights it may have to a speedy trial pursuant to the Fifth or Sixth Amendments to the United States Constitution, 18 U.S.C. §3161, Federal Rule of Criminal Procedure 48(b), any applicable local rule of the United States District Court for the District of Massachusetts, or any other applicable legal or equitable principle. SDS's agreements herein are knowing and voluntary and in express reliance on the advice of counsel.

12. The decision as to whether conduct and statements of any individual will be imputed to SDS for the purpose of determining whether SDS has committed a Breach shall be in the sole reasonable discretion of the USAO.
13. Should the USAO determine that SDS has committed a Breach, the USAO shall provide written notice to SDS of the alleged breach and provide SDS with a two-week period in which to make a presentation to the USAO to demonstrate (a) that no Breach has occurred, (b) that the Breach is not a knowing breach, or (c) that the Breach has been cured. The parties hereto expressly understand and agree that should SDS fail to make a presentation to the USAO within a two-week period, it shall be conclusively presumed, at the USAO's option, that SDS has committed a Breach. In the event of a Breach that results in a prosecution of SDS, such a prosecution may be premised upon any information provided by or on behalf of SDS to the USAO at any time, unless otherwise agreed to at the time the information was provided.
14. SDS agrees that in the event that the USAO, in its sole reasonable discretion, determines that SDS has committed a Breach: (a) SDS will not contest the filing of the Information or the admissibility into evidence of the Statement of Facts as binding admissions of SDS; (b) SDS will not contradict the contents of the Information or the Statement of Facts; (c) all statements made by or on behalf of SDS and any employee (current or former), or any testimony given by SDS and any employee (current or former) before a grand jury or elsewhere, and any leads derived from such statements and testimony, shall be admissible in evidence against SDS if proffered by the USAO in any criminal proceedings brought by the

USAO against SDS; (d) SDS shall not assert any claim under the U.S. Constitution, the rules of evidence, common law or any other legal or equitable principle, that statements made by or on behalf of SDS prior to or subsequent to this Agreement, or any leads therefrom, are inadmissible or should be suppressed; (e) SDS shall not assert that the conduct set forth in the Statement of Facts fails to provide a sufficient factual or legal basis to support the charge set forth in the Information; and (f) SDS shall not assert any legal or factual challenge to the crime charged under 21 U.S.C. §333(e) in the Information attached hereto as Appendix B.

15. SDS agrees that the consequences for a Breach as set forth in this Agreement, including without limitation, those set forth in paragraph 2 of this Agreement, are remedies to which the USAO is entitled in the event of a Breach and shall survive in the event of a Breach. SDS further agrees that the USAO's remedies for a Breach are not limited to those set forth in this Agreement. SDS further agrees that in the event of a Breach, SDS shall nevertheless be bound by its waivers of any legal, equitable or constitutional rights set forth in this Agreement, and those provisions shall survive even in the event of a Breach.

**G. Merger and Sale of SDS**

16. SDS agrees that if it sells or merges all or substantially all of the business operations as they exist as of the date of this Agreement, it shall include in any contract for sale or merger a provision binding the purchaser/successor to the obligations described in this Agreement.

**H. Agreement Binding Only on SDS and USAO**

17. The parties understand and acknowledge that this Agreement is binding on SDS and the USAO, but specifically does not bind any other federal agencies, or any state or local law enforcement or licensing authorities.
18. Nothing in this Agreement restricts in any way the ability of the USAO from proceeding against any individual or entity not a party to this Agreement.

**I. Term of Agreement**

19. This Agreement expires thirty-six (36) months from the Effective Date; provided that if on the Effective Date the USAO or any other federal law enforcement or regulatory agency with which the USAO has directed SDS to cooperate is then conducting any investigation, prosecution or proceeding relating to the Subject Matters, then paragraph six (6) of this Agreement shall expire on the date that any such investigation, prosecution or proceeding is finally terminated, as determined by the governmental department or agency conducting the investigation,


prosecution or proceeding. Between thirty (30) and sixty (60) calendar days before the expiration of this Agreement, SDS shall submit to the USAO a written certification that SDS is in compliance with this Agreement.

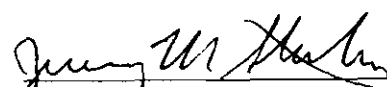
**K. Miscellaneous**

20. SDS and the USAO agree that this Agreement, including Appendix A and Appendix B, shall be made available to the public.
21. SDS warrants and represents that its Board of Directors has duly authorized, in a specific resolution, the execution and delivery of this Agreement by SDS, and that the person signing the Agreement has authority to bind SDS. SDS further agrees that it will deliver concurrently with an executed copy of the Agreement a copy of the requisite corporate resolution authorizing it to enter into this Agreement.
22. This Agreement (including Appendix A and Appendix B) constitutes the entire agreement, and supercede all other prior agreements or understandings, both oral and written, among the parties with respect to the subject matter hereof.
23. This Agreement may not be modified except in writing signed by the parties.
24. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same agreement. The exchange of copies of this Agreement and of signature pages by facsimile or electronic transmission shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile or electronic transmission shall be deemed to be their original signatures for all purposes.
25. The headings in this Agreement are for reference only and shall not affect in any way the meaning or interpretation of this Agreement.



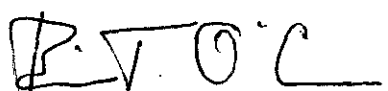
26. SDS agrees that should a dispute between SDS and the USAO arise as to the meaning of any provision of this Agreement, any ambiguities as to the terms of this Agreement shall be construed in favor of the USAO.
27. The Effective Date shall be the date upon which this Agreement is fully executed by the parties.

  
MICHAEL J. SULLIVAN  
United States Attorney

  
Jeremy M. Sternberg  
Assistant U.S. Attorney

Specialty Distribution Services, Inc.

By: Edward A. Carver  
Title: President SDS  
Date: 9/12/07

  
Brien T. O'Connor  
Counsel to Specialty Distribution Services, Inc.  
Counsel to Express Scripts, Inc.  
Date: 9/14/07

## **EXHIBIT A**

## **APPENDIX A**

### **STATEMENT OF FACTS**

1. During the relevant time period (October 1, 2000 through December 31, 2005), **SPECIALTY DISTRIBUTION SERVICES, INC. (“SDS”)** was a wholly owned corporate subsidiary of Express Scripts, Inc., a Delaware corporation with publicly traded shares on the NASDAQ exchange under the ticker symbol ESRX. **SDS** had offices in the State of Missouri.
2. **SDS** was in the business of providing distribution services for certain specialty drugs (such as injectable drugs, infused drugs and other drugs that require special handling and/or distribution).
3. Human growth hormone was a specialty drug. It was generally delivered by injection. Human growth hormone was an expensive drug; an annual dose costs up to \$20,000 per year.
4. The distribution of human growth hormone was governed by, among other statutes and regulations, the Food, Drug & Cosmetics Act, specifically 21 U.S.C. §333(e).
5. **SDS** entered into a contract, in or about October of 2000, to manage distribution of human growth hormone for a pharmaceutical company that manufactured and sold human growth hormone nationwide.
6. At all relevant times, the human growth hormone that **SDS** contracted to distribute was approved by the United States Food & Drug Administration for only the following indications:
  - long term treatment of children with growth failure due to inadequate secretion of endogenous growth hormone;
  - long term replacement therapy in adults with growth hormone deficiency, of either childhood or adult-onset etiology, as demonstrated by an appropriate Growth Hormone Stimulation Test;

## APPENDIX A

- treatment of children with Prader-Willi Syndrome; and
- long term treatment of growth failure in children born small for gestational age who fail to manifest catch-up growth by two years of age.

7. The human growth hormone that **SDS** contracted to distribute was not and never has been approved by the United States Food & Drug Administration for any cosmetic, athletic performance enhancement or anti-aging uses. In fact, no growth hormone product has ever received any such approval.

8. In or about November 2000, senior management of **SDS** discussed various “Fraud and Abuse Issues” as they related to the recently commenced human growth hormone distribution contract between **SDS** and the pharmaceutical manufacturer. One of the “Fraud and Abuse Issues” that was discussed by senior management at that time was that **SDS** was responsible for ensuring that human growth hormone was not distributed for anti-aging purposes.

9. At all relevant times, **SDS** employed pharmacists who were responsible for reviewing and filling the human growth hormone prescriptions that **SDS** received from physicians.

10. **SDS** employees, including pharmacists, reviewed certain prescriptions or statements of medical necessity for human growth hormone that stated that the reason for the prescription was “anti-aging.” **SDS** distributed human growth hormone in response to these prescriptions or statements of medical necessity.

11. **SDS** employees, including pharmacists, reviewed and filled prescriptions for well-known athletes and entertainers. **SDS** employees sometimes discussed whether the athletes or entertainers referenced in this Appendix A were taking the human growth hormone for performance enhancement, cosmetic or anti-aging purposes. Based on the identity of certain

## APPENDIX A

athletes and entertainers and the statements in their prescriptions or statements of medical necessity, SDS employees knew or should have known that SDS was distributing human growth hormone for cosmetic, anti-aging or athletic performance enhancement purposes.

12. SDS failed to train its pharmacists and other employees responsible for reviewing and approving prescriptions and processing orders of human growth hormone that the prescription could not be filled and shipped if the intended use was athletic performance, cosmetic or anti-aging.

13. Unlike most of the individuals who purchased and received human growth hormone through SDS for FDA-approved indications, the individuals who purchased human growth hormone through SDS for athletic performance, cosmetic or anti-aging purposes did so without health insurance coverage and instead paid for the drug out of their own pocket (generally by credit card).

14. On or about January 2, 2002 and October 24, 2003, SDS distributed human growth hormone, pursuant to a physician request, to a well-known professional athlete in Massachusetts. Employees of SDS knew or had reason to know that the intended use by this individual was athletic performance enhancement.

15. On or about March 11, 2002, SDS distributed human growth hormone to an entertainer pursuant to a "Physician Certification" that stated: "Rx @ Pt's Request – Not Medically Necessary." The "Physician Certification" was signed by a doctor whose medical practice is identified in writing as "Anti-Aging Clinic." Employees of SDS knew or had reason to know that the intended use by this individual was cosmetic or anti-aging.

## **APPENDIX A**

16. On or about July 22, 2002, **SDS** distributed human growth hormone to an entertainer pursuant to a "Physician Certification" that stated: "elective." Employees of **SDS** knew or had reason to know that the intended use by this individual was cosmetic or anti-aging.

17. On or about January 24, 2003, **SDS** distributed human growth hormone to an entertainer/athlete pursuant to a physician's Statement of Medical Necessity that stated this patient was 6 feet, 5 inches tall and weighed 276 pounds. The dosing approved by and shipped by **SDS** was 2.0 mg daily, a dosage typically used for athletic performance enhancement, not any adult growth hormone deficiency. Employees of **SDS** knew or had reason to know that the intended use by this individual was for athletic performance enhancement and/or cosmetic or anti-aging.

18. **SDS** knowingly distributed human growth hormone, as enumerated in paragraphs 14 through 17 herein, for a use in humans other than the treatment of a disease or other recognized medical condition, where such use had been both authorized by the Secretary of Health and Human Services and made pursuant to the order of a physician, in violation of 21 U.S.C. §333(e).

## **EXHIBIT B**

**APPENDIX B**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	CRIMINAL NO.
	)	
v.	)	VIOLATION:
	)	
SPECIALTY DISTRIBUTION	)	
SERVICES, INC.	)	21 U.S.C. §333(e) (illegal distribution of human
	)	growth hormone)
Defendant.	)	
	)	

**INFORMATION**

The United States Attorney charges that:

**COUNT I**

At all times material hereto, unless otherwise alleged:

**The Defendant**

1. **SPECIALTY DISTRIBUTION SERVICES, INC.** was a wholly owned corporate subsidiary of Express Scripts, Inc., a Delaware corporation with publicly traded shares on the NASDAQ exchange under the ticker symbol ESRX. Both **SPECIALTY DISTRIBUTION SERVICES, INC.** and Express Scripts, Inc. had offices in the State of Missouri. Throughout this Information, **SPECIALTY DISTRIBUTION SERVICES, INC.** and its corporate affiliates will be referred to as **SDS**.

2. **SDS** was in the business of providing distribution services for certain specialty drugs (such as injectable drugs, infused drugs and other drugs that require special handling and/or distribution).



## **APPENDIX B**

### **Background**

3. Human growth hormone was a specialty drug distributed by **SDS**.

4. The distribution of human growth hormone was governed by the Food, Drug & Cosmetics Act, specifically 21 U.S.C. §333(e).

5. The human growth hormone that **SDS** contracted to distribute in 2000 was only approved by the United States Food & Drug Administration ("FDA") for certain growth deficiencies and was not, and never has been, FDA approved for any cosmetic, athletic performance enhancement or anti-aging uses.

6. **SDS** employees filled prescriptions for and distributed human growth hormone to certain well-known athletes and entertainers for cosmetic, athletic performance enhancement or anti-aging uses.

7. On or about January 2, 2002, May 11, 2002, July 22, 2002, January 24, 2003 and October 24, 2003, within the District of Massachusetts and elsewhere, the Defendant

#### **SPECIALTY DISTRIBUTION SERVICES, INC.**

knowingly distributed and possessed with intent to distribute, human growth hormone for a use in humans other than the treatment of a disease and other recognized medical condition, where such use had been authorized by the Secretary of Health and Human Services and pursuant to the order of a physician.

## **APPENDIX B**

All in violation of Title 21, United States Code, Section 333(e).

MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY

By: \_\_\_\_\_  
Jeremy M. Sternberg  
Susan G. Winkler  
Assistant U.S. Attorneys